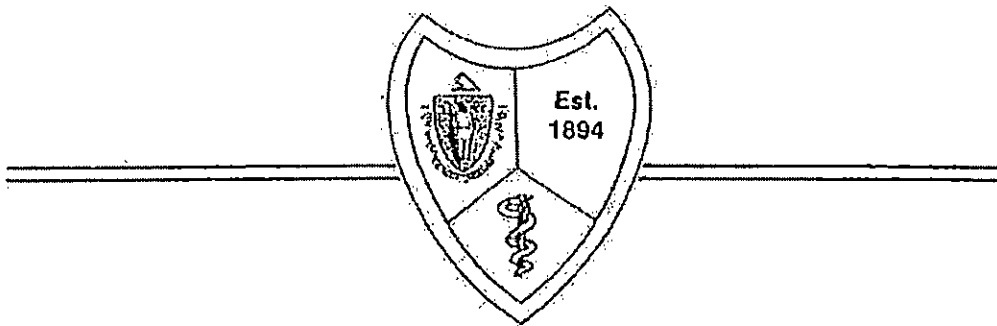


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BOARD OF REGISTRATION IN MEDICINE**

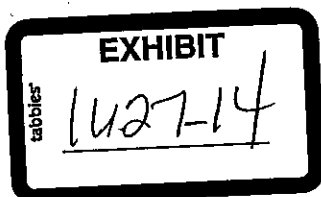


**Prescribing Practices
Policy and Guidelines**

**Adopted August 1, 1989
Amended November 17, 2010**

Notice

**Policy 89-01: The Prescribing Practices Policy and
Guidelines (Adopted August 1, 1989; Amended
November 17, 2010) supersedes all previous versions
of these Guidelines.**



**LARKIN
EXHIBIT 14**

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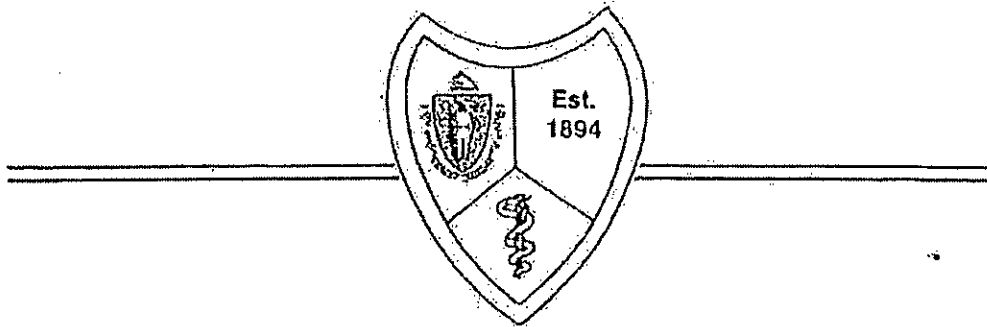


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INTRODUCTION AND EXECUTIVE SUMMARY

The Massachusetts Board of Registration in Medicine has prepared these “Prescribing Practices Policy and Guidelines” to provide physicians with greater understanding of their responsibilities and the standards the Board applies in reviewing their prescribing practices. The Board hopes that, by providing a comprehensive overview of the physician’s responsibilities related to prescribing, this publication will help further its overall mission to foster the delivery of competent, high quality health care in Massachusetts. The Board hopes that this information will help physicians maintain a high level of quality in their prescribing practices.

The Board is aware that the area of prescribing changes rapidly, and will update this publication appropriately, to reflect changes in the laws related to prescribing and to the understanding of best practices. This publication is available on the Board’s website at www.massmedboard.org, where periodic updates will be placed. Physicians are encouraged to check the website regularly for the latest revisions. In addition to this publication, the Board has issued other policies and guidelines related to prescribing practices. These are available on the Board’s website, and are also attached to this publication as appendices.

This Executive Summary of the Guidelines is provided as a short review of the material contained in the Guidelines. Please refer to each individual section for more comprehensive information.

Part I – Technical Requirements

Part I of this publication summarizes the practical and technical requirements related to prescribing.

Section 1: Registration

Prior to prescribing any controlled substance in Massachusetts, physicians should:

- Have a Massachusetts license
- Register with the United States Drug Enforcement Agency (DEA) to prescribe substances in Schedules II-V
- Obtain a Massachusetts Controlled Substance Registration (MCSR) number to prescribe substances in Schedules II-VI (in Massachusetts, all prescription drugs are considered controlled)

The Board expects physicians to be aware of and comply with the registration requirements of both DEA and DPH. These requirements are summarized in Part I, Section 1 of these Guidelines.

Special authorization from the DEA is necessary to be considered a narcotic treatment program. Physicians who wish to run a narcotic treatment program must:

- Be separately registered with the DEA as a narcotic treatment program
- Comply with all DEA regulations regarding drug addiction treatment
- Be licensed by the Massachusetts DPH as a substance abuse treatment program
- Obtain a DEA waiver to treat opioid addiction outside a treatment program if a physician wants to prescribe in the office setting, for example.

Part 2: Drug Schedules

In Massachusetts all prescription medications are controlled substances. This section describes each of the six schedules, and lists examples of the drugs in each Schedule.

Part 3: Prescriptions

This section sets out the requirements for issuing prescriptions, including verbal, faxed, and electronic prescriptions.

Part 4: Dispensing

This section sets out the requirements for dispensing controlled substances.

Part 5: Supervision of Other Health Care Professionals Engaged in Prescriptive Practices

Mid-level practitioners

Mid-level practitioners, such as advanced practice registered nurses and physician assistants may issue orders for a controlled substance in the course of professional practice.

Their prescriptive practices must be supervised by a Massachusetts licensed physician.

- Advanced practice registered nurses
 - The supervising physician must have an unrestricted full license in the Commonwealth, have appropriate experience related to the advanced practice registered nurse's area of practice, and have a valid DEA certificate of registration and MCSR number.
 - The supervising physician and advanced practice registered nurse must sign mutually developed and agreed-upon guidelines, and the physician must review the nurse's prescriptive practice and provide ongoing direction to regarding the prescriptive practice. The written guidelines must specify the types of medications to be prescribed, any limitations on prescriptions, and when referral or physician consultation is required.
 - There must be specific protocols for the initiation of intravenous therapies and Schedule II drugs. The physician must review the initial prescription of Schedule II drugs within 96 hours of the prescription.
- Physician Assistants
 - The supervising physician must have an unrestricted full license in the Commonwealth, have appropriate experience related to the physician assistant's area of practice, and have a valid DEA certificate of registration and MCSR number.
 - The physician and physician assistant must sign mutually developed and agreed-upon guidelines and the physician must review the physician assistant's prescriptive practice and provide ongoing direction to the physician assistant. The guidelines must include any limitations on medications to be prescribed, and describe the circumstances in which physician consultation and referral is required.
 - The guidelines must include protocols for the initiation of intravenous therapies and Schedule II drugs. In addition, the guidelines must specify the frequency of review, and in the case of prescriptions for Schedule II controlled substances, the physician must review the prescription within 96 hours after its issuance. The use of pre-signed prescription blanks or forms is prohibited.

Pharmacists

In January, 2009, the Commonwealth enacted the Collaborative Drug Therapy Management Act, which permits certain pharmacists and physicians to enter into a collaborative practice agreement, under which the pharmacist may then initiate, monitor, modify and discontinue a patient's drug therapy.

Collaborative practice agreements are permitted in the following settings:

- Hospitals;
- Long Term Care facilities;
- Licensed inpatient or outpatient hospice settings;
- Certain ambulatory care clinics; or
- Certain community retail drug businesses, for certain chronic illnesses.

The collaborative practice agreement must specifically name each disease being co-managed by the pharmacist and physician. A patient must be referred by a supervising physician to that physician's collaborating pharmacist, must be given notice of the collaboration and must, as appropriate to the setting of the agreement, consent to the collaboration. Any collaborative practice agreement in the retail drug business setting may only permit the prescription of Schedule VI controlled substances.

Section 6: Gifts Or Inducements From The Pharmaceutical Industry

The Commonwealth takes seriously the potential for impropriety or the appearance of impropriety which may occur when pharmaceutical companies or medical device manufacturers give gifts to physicians. This section discusses the AMA's ethical opinion on gifts from those industries, and reviews the Massachusetts law, aimed at pharmaceutical and medical device manufacturing companies, prohibiting certain gifts to physicians.

Part II - Boundaries of Acceptable Medical Practice

Part II provides guidance on the legal standards and boundaries applicable to prescribing in medical practices.

Section 1: Basic Requirements of Acceptable Medical Practice

To be valid, a prescription must be issued for a legitimate medical purpose, by a practitioner in the usual course of his or her professional practice. As with every aspect of medical care, a physician's prescription practices should be guided by medical knowledge, best-practices, guidelines and consensus standards. The Board encourages physicians to understand their roles and responsibilities in preventing medication errors.

Section 2: Prescribing to Immediate Family Members

Board regulations prohibit physicians, except in an emergency, from prescribing Schedule II controlled substances to a member of his immediate family.

Section 3: Prescribing to Self

Physicians are prohibited from prescribing controlled substances in Schedules II through IV for their own use.

Section 4: Internet Prescribing

The Board has issued Policy No. 03-06 – "Internet Prescribing." The policy states that to be valid, a prescription must be issued in the usual course of the physician's professional practice, and within a physician-patient relationship that is for the purpose of maintaining the patient's well-being. In addition, the physician must conform to certain minimum standards of patient care, such as taking an adequate medical history, doing a physical or mental status examination and documenting the findings. Issuance of a prescription, by any means, including the Internet or other electronic process, that does not meet these requirements is therefore unlawful.

Section 5: Prescribing for the Treatment of Pain

The FSMB has issued a Model Policy for the Use of Controlled Substances for the Treatment of Pain (Model Policy), which the Board adopted in December, 2004.

The Board encourages physicians to read and follow the policy, in treating patients' pain.

Section 6: Treating Drug-Dependent Persons

Treating patients for drug dependency usually requires specialized knowledge beyond the typical substance abuse training that is taught in medical school. Physicians should not undertake to treat patients for drug dependency or the psychological underpinnings of an addictive personality unless they have sufficient training to do so. Where the treating physician lacks specialized knowledge, patients should be referred to experts in drug dependency.

Physicians who use drugs to treat drug dependency are subject to special requirements under Massachusetts and federal laws. Physicians interested in operating an opioid treatment program to provide Schedule II controlled substances for the treatment of opioid (narcotic) addiction should review Part I, Section 1, "Special Authorizations Required to Treat Addiction," and Part II, Section 7, "Office-Based Treatment of Opioid Addiction."

Physicians who are not specially registered with the DEA are permitted to administer narcotics to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment.

Section 7: Office-Based Treatment of Opioid Addiction

Before any physician can treat opioid addicted patients in an office-based setting, the physician must apply for a waiver. See Part I, Section 1, "Special Authorizations Required to Treat Addiction." Once a physician has received that waiver, the Board expects that the

physician will work within the boundaries of accepted professional practice for office-based treatment of opioid addiction.

Section 8: Enhancing Patient Compliance

This section discusses means for enhancing patient compliance with prescriptions.

Section 9: The Importance of Continuing Medical Education

Many physicians engage in improper and uninformed prescribing practices simply because they have not kept abreast of new developments in pharmacology and drug therapy. The Board urges all physicians to keep up-to-date on current information that affects the proper prescribing of controlled substances by taking Continuing Medical Education Courses.

Part I – Technical Requirements

1. REGISTRATION REQUIREMENTS

In Massachusetts, all prescription drugs are controlled substances.¹ Therefore, to prescribe or dispense any type of prescription drug, physicians who practice medicine in Massachusetts must obtain a Massachusetts Controlled Substances Registration (MCSR) number from the Massachusetts Department of Public Health (DPH).² Additionally, all physicians who prescribe any controlled substance in Schedules II through V must also have a registration certificate from the United States Drug Enforcement Administration (DEA).³ Physicians may not prescribe Schedule I controlled substances, which have no current accepted medical use.⁴ Physicians who issue prescriptions only for Schedule VI drugs must have a MCSR number but are not required to register with the DEA.

DEA registration is based on a physician's compliance with state law, including state licensing and registration requirements.⁵ Therefore, the MCSR number must be obtained prior to applying for a certificate of registration from DEA.

The DPH Drug Control Program is responsible for issuing MCSR numbers. To obtain an application for an MCSR number and information about the application process, contact the DPH Drug Control Program. *See* Appendix A, "Contact Information." To obtain an application for a certificate of registration from DEA, instructions and a copy of the "DEA Practitioner's Manual," physicians should contact the DEA Boston Field Office. *See* Appendix A, "Contact Information."

¹ Massachusetts General Law c. 94C, § 2(a); 105 Code of Massachusetts Regulations 700.002(F). Prescription drugs in Schedule VI are controlled substances in Massachusetts, but are not controlled by the DEA.

² M.G.L. c. 94C, § 7, 105 CMR 700.004(M).

³ 21 United States Code 823 and 21 CFR 1301.

⁴ M.G.L. c. 94C, § 3. *See infra* Part I, Section 2, "Drug Schedules."

⁵ 21 USC 823(f) and 21 Code of Federal Regulations 1306.03(a). Physicians who practice in other states must obtain separate DEA Registration numbers for each state in which they practice. Physicians who practice in other states should check with each state about that state's prescribing laws.

In order to prescribe drug treatment for opioid addiction, physicians must obtain additional specific authorization from the DEA, the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), and the Massachusetts Bureau of Substance Abuse Services (BSAS).⁶

Registration Requirements

Basic Requirements

Physicians who practice at only one location need only one MCSR number and one DEA registration certificate to prescribe. Physicians who dispense or administer controlled substances at more than one location must have a separate MCSR number and a separate DEA registration certificate for each location.⁷

Physicians must obtain separate MCSR numbers for each of their professional activities. For example, separate registrations would be required for work as a researcher and as a practicing physician or chemical analyst.⁸ The DEA does not require separate registrations for each professional activity.⁹

Change of Address

Because DEA certificates of registration and MCSR numbers are location-specific, physicians must notify the DEA and DPH Drug Control Program when they move from their registered address.

A physician's DEA registration may be transferred to a new location. A physician's request for transfer must be made to the DEA in writing and must be accompanied by

⁶ See *infra* Part I, Section 1, "Special Authorizations Required to Treat Addiction" for further discussion.

⁷ 21 USC 822(e); M.G.L. c. 94C, § 10.

⁸ 105 CMR 700.004(A)(2) and 105 CMR 700.004(C).

⁹ 21 USC 823(f).

photocopies of the physician's medical license, MCSR number, and DEA registration certificate.¹⁰

MCSR numbers are not transferrable to a new location, and physicians must apply for a new registration prior to moving.¹¹ Physicians must also notify the DPH Commissioner 30 days in advance of his or her discontinuation of business or professional practice.¹²

Registration Renewal and Termination

DEA registration must be renewed every three years.¹³ The DEA notifies registrants in advance of the renewal date.

The Commissioner of DPH periodically recalls MCSR numbers. Currently, the Commissioner recalls numbers every three years. The Commissioner notifies physicians of the intended recall, and, upon receipt of the notification, the physician must respond to the recall to maintain his or her MCSR number.¹⁴

The following conditions will result in termination of the MCSR number:

- A change of name or address as shown on the registration,
- Discontinuation of business or professional practice in Massachusetts,
- Revocation of registration by the DPH Commissioner, or
- Death of the registrant.¹⁵

Physicians should note, there is no provision for physicians who discontinue their business or professional practice in Massachusetts to remain registered in the state, even if they maintain a home in the state or maintain other contacts with the state. Physicians must apply for a new MCSR number if they return to Massachusetts to practice.

¹⁰ 21 CFR § 1309.63.

¹¹ 105 CMR 700.004(J)(1).

¹² 105 CMR 700.004(J)(2).

¹³ 21 USC 822(a)(2).

¹⁴ G.L. c. 94C, § 7(f); 105 CMR 700.004(D).

¹⁵ 105 CMR 700.004(J).

Physicians Exempt from Registration Requirements

Limited Licensees

Limited licensees (residents and clinical fellows) do not need a MCSR number or DEA registration.¹⁶ Limited licensees may "administer, prescribe or otherwise dispense controlled substances . . . under the registration of the hospital or other registered health facility by which they are employed."¹⁷ Limited licensees may only do so, however, if the dispensing, administering or prescribing is done in the usual course of professional practice and only within the scope of their employment in the facility; and he or she is specifically authorized by the facility to do so.¹⁸

Federal Government Physicians

The DEA registration requirements are waived for physicians who work exclusively for a branch of the U.S. Military, the U.S. Public Health Service, or the U.S. Bureau of Prisons.¹⁹ Such physicians must put their service identification number on all prescriptions, however, and should consult with their agency's administrators regarding other requirements.²⁰

Special Authorizations Required to Treat Addiction

The DEA defines a narcotic treatment program as "a program engaged in maintenance and/or detoxification treatment with narcotic drugs."²¹

Prescribing Schedule II Controlled Substances to Treat Opioid Addiction

An individual physician may only prescribe methadone or any other Schedule II controlled substance for purposes of treating opioid addiction if the physician is registered with

¹⁶ 21 USC 822(c)(1); 105 CMR 700.004(B)(5).

¹⁷ 105 CMR 700.004(B)(5).

¹⁸ 105 CMR 700.004(B)(5).

¹⁹ 21 CFR 1301.22 and 1306.05

²⁰ 21 CFR 1306.01 *et. seq.*

²¹ 21 CFR 1300.01(31).

the DEA to run a narcotic treatment program and the physician is in compliance with DEA regulations regarding treatment.²²

All "Substance Abuse Treatment Programs" operating in Massachusetts must be licensed by the Department of Public Health.²³ Physicians interested in operating an opioid treatment program to provide Schedule II controlled substances for the treatment of opioid (narcotic) addiction should contact the DEA, SAMHSA, and DPH to obtain the necessary applications and detailed information regarding opioid treatment program requirements. See Appendix A, "Contact Information."

Prescribing Schedule III – V Controlled Substances to Treat Opioid Addiction

Physicians who have specific expertise and meet the qualifications set by DEA and the Substance Abuse and Mental Health Services Administration (SAMHSA), can receive a waiver permitting them to treat opioid addiction in their offices rather than in substance abuse treatment programs. Physicians who have been approved for such a waiver may use certain narcotic medications in Schedules III, IV, and V, which have been approved by the U.S. Food and Drug Administration (FDA) for opioid addiction treatment.²⁴ Currently, the only narcotic medications approved by the FDA for such waivers are two Schedule III controlled substances: Subutex® (buprenorphine hydrochloride) and Suboxone® tablets (buprenorphine hydrochloride and naloxone hydrochloride). During their first year under such a waiver, physicians are permitted to treat no more than 30 patients. After one year, physicians may submit a notification of the need and intent to treat up to 100 patients.²⁵

²² 21 CFR 1306.07(a).

²³ M.G.L. c. 111B, §§6, 6A, 6B; M.G.L. c. 111E § 7; and 105 CMR 164.000

²⁴ The Drug Addiction Treatment Act of 2000 (DATA 2000), 21 USC 801. See also 21 CFR 1306.67(d) (administration or dispensing of narcotic drugs).

²⁵ 21 USC § 823(g)(2).

2. DRUG SCHEDULES

The general rule that a prescription must be issued in the usual course of a practitioner's practice and for a legitimate medical purpose applies to all controlled substances.²⁶ There must be a physician-patient relationship that is for the purpose of maintaining the patient's health and the physician must conform to generally accepted standards of patient care, including documentation of the patient's current complaint, medical history, physical examination, appropriate diagnosis and treatment plan.²⁷

Schedule I

Schedule I controlled substances consist of opiates, opium derivatives and hallucinogenics²⁸ that have no current accepted medical use, lack safety standards for use under medical supervision, and have a high potential for abuse.²⁹ Physicians may conduct bona fide research with Schedule I controlled substances with the approval of the Secretary of Health and Human Services, the Attorney General of the United States and the DPH Commissioner.³⁰ The requirements for using Schedule I controlled substances for research are quite restrictive and any physician who is interested in such research should consult with both the DEA and DPH for further information.

Some examples of Schedule I controlled substances include: heroin, lysergic acid diethylamide (LSD), marijuana, and Gamma Hydroxybutyric Acid (GHB).³¹

²⁶ M.G.L. c. 94C, §19(a).

²⁷ See *infra* Part II, I, "Basic Requirements of Acceptable Medical Practice" for further discussion of this expectation.

²⁸ 21 USC 812(c), M.G.L. c. 94C, §3(1).

²⁹ 21 USC 812(b)(1); M.G.L. c. 94C, §3(1).

³⁰ 21 USC 823(f); 105 CMR 700.004(G).

³¹ 21 USC 812(c).

Schedule II

Schedule II controlled substances are considered to have a high potential for abuse, which may lead to severe psychological or physical dependence.³²

Schedule II prescriptions may only be issued for a thirty-day supply of medication.³³

There are two exceptions to this law:

- Prescriptions for methylphenidate and single entity drug products containing dextroamphetamine sulphate and methylphenidate hydrochloride may be issued for up to a sixty-day supply when used for the treatment of inattention, impulsivity-hyperactivity disorder or narcolepsy; and
- Prescriptions for implantable infusion pumps containing a Schedule II controlled substance may be issued for a ninety day supply.³⁴

Refills of Schedule II drugs are not permitted.³⁵ Physicians may provide a patient with multiple prescriptions for the same Schedule II controlled substance for a total of up to a ninety day supply.³⁶ To comply with this federal law, the DPH Drug Control Program, the Board of Registration in Pharmacy, and the Board of Registration in Medicine have adopted a "Joint Policy Regarding Issuance of Multiple Prescriptions for Schedule II Controlled Substances; and Joint Policy on Prescribing and Dispensing of Dextro- and Levo- Amphetamines."³⁷ Under this policy, physicians must date the prescriptions so they must be filled sequentially, with the patient receiving no more than a thirty day supply per prescription. The physician must indicate on

³² 21 USC 812(b)(2); M.G.L. c. 94C, §3(2).

³³ M.G.L. c. 94C, §23.

³⁴ M.G.L. c. 94C, §23(d).

³⁵ 21 USC 829; M.G.L. c. 94C, § 23(b).

³⁶ 21 CFR 1306.

³⁷ This policy is attached at Appendix C.

subsequent prescriptions a "Do Not Fill Before" date, and must indicate the actual date that the prescription is signed.

Schedule II controlled substances may not be prescribed without a written prescription except in emergency situations. "Emergency situations," are defined as "situations in which the practitioner who intends to prescribe a controlled substance in Schedule II determines: (a) that the immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user, and (b) that no appropriate alternative treatment is available, including administration of a controlled substance which is not in Schedule II, and (c) that it is not reasonably possible for the practitioner to provide a written prescription to be presented to the person dispensing the controlled substance prior to the dispensing."³⁸ Pharmacists may not fill verbal prescriptions for Schedule II substances in a quantity exceeding that which is "adequate to treat the patient during the emergency period."³⁹ A verbal prescription for a Schedule II drug must be written and filed with the pharmacy within seven days of the event and the prescription should have written on its face, "Authorization for Emergency Dispensing."⁴⁰

For ambulatory patients, Schedule II substances may be faxed to pharmacies, but a hard copy prescription must accompany the patient before the medication can actually be dispensed.⁴¹

The Board strongly urges physicians to see patients who are using Schedule II drugs for long-term treatment as often as possible and suggests that patients be clinically re-evaluated at least once every four months. Documentation should be placed in the record if this is impossible, impractical or inappropriate. As a best practice, the physician should speak with the patient or the patient's primary physician by telephone before issuing a new Schedule II

³⁸ 247 CMR 5.03(1). The Federal definition of "emergency situations," from which the Massachusetts regulation was derived, can be found in 21 CFR 290.10.

³⁹ 21 CFR 1306.11(d)(1).

⁴⁰ 21 CFR 1306.11(d)(4); M.G.L. c. 94C; §20(c); and 247 CMR 5.03(3).

⁴¹ 21 CFR 1306.11(a).

prescription.⁴² It is the Board's position that when a primary care physician and a specialist are both treating a patient, it is the specialist who is obligated to inform the primary physician as to any treatment rendered to a mutual patient.

Because of their extremely high potential for abuse, Schedule II controlled substances may not be prescribed to a member of a licensee's immediate family, except in an emergency.⁴³ The Board also has prohibited physicians from prescribing controlled substances in Schedules II through IV for their own use.⁴⁴

Some examples of Schedule II narcotics include morphine, codeine, hydromorphone, methadone,⁴⁵ meperidine, oxycodone, oxymorphone and fentanyl. Schedule II stimulants include amphetamine, methamphetamine and methylphenidate.⁴⁶

Schedule III

Schedule III controlled substances have a potential for abuse, that is somewhat lower than substances in Schedules I or II. Abuse of Schedule III substances may lead to moderate or low physical dependence or high psychological dependence.⁴⁷

Schedule III prescriptions may be issued for up to a thirty-day supply with an exception for implantable infusion pumps with a Schedule III substance which may be filled with a maximum of a ninety-day supply.⁴⁸

⁴² See "Responsible Opioid Prescribing, A Physician's Guide", Scott M. Fishman, M.D., Federation of State Medical Boards, 2007.

⁴³ 243 CMR 2.07(19).

⁴⁴ 243 CMR 2.07(19).

⁴⁵ Methadone may only be prescribed as an analgesic. Methadone is available for treatment of opiate addiction only at federally regulated opiate treatment programs.

⁴⁶ 21 USC 812(c).

⁴⁷ 21 USC 812(b)(3); MGL c. 94C § 3(3).

⁴⁸ M.G.L. c. 94C § 23(d).

Schedule III prescriptions may be refilled up to five times within six months of the date of the prescription.⁴⁹ Controlled substances that are prescribed without an indication for refills cannot be refilled without authorization by the prescriber.

A Schedule III drug may be prescribed verbally in the absence of an emergency, but the prescription must be written and filed with the pharmacy within seven days.⁵⁰ Prescriptions for Schedule III substances may also be faxed. A follow-up hard copy does not need to be filed with the pharmacy.

The Board believes that good medical practice requires a physician to see a patient at least once every six months when prescribing a controlled substance over a long period of time. If this is impractical, inappropriate or impossible, an explanation should be recorded in the patient's chart. These instances should be extremely rare.

The Board has prohibited physicians from prescribing controlled substances in Schedule III for their own use.⁵¹

Some examples of Schedule III controlled substances include: Subutex® and Suboxone®⁵²; combination products containing less than 15 milligrams of hydrocodone per dosage unit, such as Vicodin®, Lortab®, and Lorcet®; combination products containing not more than 90 milligrams of codeine per dosage unit, such as Tylenol with Codeine®; ketamine, benzphetamine hydrochloride, phendimetrazine tartrate, dronabinol, and anabolic steroids such as oxandrolone.⁵³

⁴⁹ 21 USC 829 (b).

⁵⁰ M.G.L. c. 94C § 17(c) and M.G.L. c. 94C § 20(c).

⁵¹ 243 CMR 2.07(19).

⁵² Subutex® and Suboxone® and approved generic equivalents require a DATA-waiver and a unique identification number for office-based opiate addiction treatment.

⁵³ 21 USC 812(c).

Schedule IV

Schedule IV controlled substances have a low potential for abuse relative to the substances in Schedule III, but may lead to limited physical or psychological dependence.⁵⁴ Schedule IV prescriptions may be refilled up to five times within six months of the date of the prescription.⁵⁵ A Schedule IV drug may be prescribed verbally in the absence of an emergency, but the prescription must be written and filed with the pharmacy within seven days.⁵⁶ Prescriptions for Schedule IV substances may also be faxed. A follow-up hard copy does not need to be filed with the pharmacy.

The Board has prohibited physicians from prescribing controlled substances in Schedule IV for their own use.⁵⁷

Some examples of Schedule IV controlled substances include: long-acting barbiturates such as phenobarbital (Luminal®), and mephobarbital (Mebaral®); ultrashort-acting barbiturates such as methohexital (Brevital®); modafinil; benzodiazepines such as estazolam (ProSom®), flurazepam (Dalmane®), temazepam (Restoril®), triazolam (Halcion®), midazolam (Versed®), alprazolam (Xanax®), diazepam (Valium®), lorazepam (Ativan®), clonazepam (Klonopin®); chloral hydrate; and dextropropoxyphene forms: Darvon®, Darvocet®, Dolene®, Propacet®, propoxyphene.

Schedule V

Schedule V controlled substances have a low potential for abuse compared to the substances in Schedule IV.⁵⁸ A Schedule V drug may be prescribed verbally in the absence of an

⁵⁴ 21 USC 812(b)(4); M.G.L. c. 94C, §3(4).

⁵⁵ 21 USC 829(b).

⁵⁶ M.G.L. c. 94C, §17(c); M.G.L. c. 94C, §20(c).

⁵⁷ 243 CMR 2.07(19).

emergency, but the prescription must be written and filed with the pharmacy within seven days.⁵⁹ Prescriptions for Schedule V substances may also be faxed. A follow-up hard copy does not need to be filed with the pharmacy.

Examples of Schedule V controlled substances include: liquid preparations of codeine used for cough suppression, Parapectolin®, Kapectolin PG®, and Lomotil®.

Schedule VI

Prescription drugs that do not fall within Schedules II through V are considered to be Schedule VI controlled substances in Massachusetts.⁶⁰ These drugs have a “R” designation in the Physicians’ Desk Reference 2010® (PDR).⁶¹ The dispensing, administering and prescribing of these drugs are subject to state regulation.

Physicians may dispense up to a 30 day supply of Schedule VI sample medications. Larger supplies of sample medications, up to 90 days, may be dispensed as part of a manufacturer’s indigent patient drug program.⁶² Physicians must label all sample medications dispensed to patients, including those provided as part of an indigent patient drug program.⁶³ Physicians who provide samples of Schedule VI drugs to their patients are required to keep a record of such dispensing.⁶⁴

As with all controlled substances, there are some Schedule VI drugs that can be misused or abused. Physicians are encouraged to visit the U.S. Department of Justice Diversion Control website to review the list of “Drugs and Chemicals of Concern.” Included on that list are two

⁵⁸ 21 USC 812(b)(5); M.G.L. c. 94C, §3(5)

⁵⁹ M.G.L. c. 94C, §17(c); M.G.L. c. 94C, §20(c).

⁶⁰ G.L. c. 94C, § 2(a); 105 CMR 700.002(F).

⁶¹ Massachusetts regulations identify the specific compounds that fall within Schedule VI. 105 CMR 701.002.

⁶² 105 CMR 700.010

⁶³ 105 CMR 700.010

⁶⁴ 105 CMR 700.006(F)(5) *See infra* Part I, Section 4, “Dispensing” for more discussion of this topic.

Schedule VI drugs: tramadol (marketed under the brand name Ultram®),⁶⁵ and butalbital with acetaminophen (marketed under the brand name Fioricet®). According to the Massachusetts Medical Society, there is anecdotal evidence that patients with a history of substance dependence can experience significant addictive symptoms with Ultram®.⁶⁶ Fioricet®, which is a Schedule VI controlled substance, contains the same active ingredient (butalbital) as Fiorinal® with aspirin, which is a Schedule III controlled substance. Since Fioricet® is in Schedule VI, its addictive potential may be overlooked.⁶⁷

⁶⁵ Ortho-McNeil, the current makers of Ultram® have added the following "Drug Abuse and Dependence" warning to their label:

Ultram® may induce psychic and physical dependence of the morphine-type (μ -opioid) . . . Dependence and abuse, including drug-seeking behavior and taking illicit actions to obtain the drug are not limited to those patients with prior history of opioid dependence. The risk in patients with substance abuse has been observed to be higher. Ultram® is associated with craving and tolerance development. Withdrawal symptoms may occur if Ultram® is discontinued abruptly. . . .

⁶⁶ "Even Schedule VI Drugs Can Be Addictive" Massachusetts Medical Society, February 25, 2009.

⁶⁷ *Id.*

3. PRESCRIPTIONS

The Prescription Slip

The Massachusetts controlled substances law states:

A practitioner who dispenses a controlled substance by issuing a written prescription shall state on the prescription the name, address and registration number of the practitioner, the date of delivery of the prescription, the name, dosage and strength per dosage unit of the controlled substance, the name and address of the patient unless it is a veterinary prescription, the directions for use and any cautionary statements required, and a statement indicating the number of times to be refilled.⁶⁸

Accordingly, every prescription written in the Commonwealth must be written on a form that contains the following:

- A signature line for the physician's signature.
- Space in which the physician may write in his or her own handwriting the words "no substitution."
- The name and address of the physician (or, in the case of a hospital or clinic prescription form, the name and address of the hospital or clinic) must be printed or typed on the form.
- The registration number of the physician;
- The date of issuance of the prescription;
- The name, dosage and strength per dosage unit of the controlled substance prescribed, and the quantity of the dosage units;
- The name and address of the patient;
- Directions for use, including any cautionary statements required; and
- A statement indicating the number of times to be refilled.⁶⁹

Tamper Resistant Prescription Law

All written prescriptions for outpatient drugs that are paid for by Medicaid must be executed on a tamper-resistant prescription.⁷⁰ To be considered tamper-resistant, a prescription pad must contain the following three characteristics:

- 1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form (for example: a high security watermark on reverse side of blank, or the use of thermochromic ink);

⁶⁸ M.G.L. c. 94C, §22(a).

⁶⁹ 105 CMR 721.020.

⁷⁰ Public Law, 110-28, U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007, Section 7002 (effective April 1, 2008).

- 2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription pad by the prescriber (for example: tamper-resistant background ink showing erasures or attempts to change written information); and
- 3) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms (for example: sequentially numbered blanks or duplicate or triplicate blanks).

In Massachusetts, the requirement applies to both prescription drugs and any over-the-counter drugs that are prescribed for MassHealth members.⁷¹

Faxing Prescriptions

For ambulatory patients, Schedule II substances may be faxed to pharmacies, but a hard copy prescription must accompany the patient before the medication can actually be dispensed.⁷² However, a hard copy follow-up prescription is not required for residential patients in either long-term care facilities or federally supported or state licensed hospice care programs.⁷³ Nor is a hard copy follow-up prescription required when the facsimile prescription calls for a narcotic to be compounded for direct administration by injection to the patient.⁷⁴ Facsimile prescriptions for Schedules III, IV, V, and VI drugs do not require the filing of a hard copy in follow-up with the pharmacy.

Electronic Prescribing

Schedule VI prescriptions may be electronically transmitted from a physician to a pharmacy.⁷⁵ The prescription or drug order shall be electronically transmitted in a manner that

⁷¹ MassHealth "All Provider Bulletin" No. 174, April, 2008.

⁷² 21 CFR 1306.11(a).

⁷³ 21 CFR 1306.11(g).

⁷⁴ 21 CFR 1306.11(e).

⁷⁵ M.G.L. c. 94C, §23(g); 247 CMR 5.02(1); 105 CMR 721.020(A)(3) and 105 CMR 721.030.

maintains patient confidentiality.⁷⁶ Such a prescription must either bear the physician's electronic signature or employ some other secure method of validation.⁷⁷

At this time, federal law does not permit any form of electronically transmitted prescriptions, except for faxed prescriptions, for Schedule II through V controlled substances. However, on March 31, 2010, the Drug Enforcement Administration (DEA) issued an Interim Rule that would allow practitioners to write prescriptions for controlled substances electronically.⁷⁸ The Interim Rule would give prescribers the option of submitting electronic prescriptions and would permit pharmacies to receive, dispense and archive electronic prescriptions. The DEA will accept comments on the Rule for 60 days from the date of issuance. The Rule is also subject to Congressional review. If there are no major changes after the comment period and Congressional review, the effective date of the Rule will be June 1, 2010.

Verbal Authorization

Schedule II controlled substances may not be prescribed without a written prescription except in emergency situations. A verbal prescription for a Schedule II drug must be written and filed with the pharmacy within seven days of being issued, and the prescription should have been written on its face, "Authorization for Emergency Dispensing."⁷⁹ Drugs in Schedules III - V may be prescribed by verbal prescription in the absence of an emergency but the prescription must be written and filed with the pharmacy within seven days. Verbal prescriptions may be communicated to a pharmacist by an expressly authorized employee or agent of the physician.⁸⁰

⁷⁶ 247 CMR 5.02(1).

⁷⁷ 105 CMR 721.030.

⁷⁸ Federal Register, Vol. 75, No. 61/Wednesday, March 31, 2010/Rules and Regulations, Drug Enforcement Administration, 21 CFR Parts 1300, 1304, 1306 and 1311.

⁷⁹ 21 CFR 1306.11(d)(4); M.G.L. c. 94C, §20(c); and 247 CMR 5.03(3).

⁸⁰ M.G.L. c. 94C, §20(c).

4. DISPENSING

The term “dispense” means deliver a controlled substance to an ultimate user or research subject by a practitioner or pursuant to the order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary for such delivery.⁸¹ A physician must have a separate DEA certificate of registration and MCSR number for each location at which he or she dispenses controlled substances.⁸²

General Requirements

Federal law permits physicians to dispense Schedule II controlled substances without a prescription only in emergency situations.⁸³ Under both Federal and Massachusetts law, physicians may dispense controlled substances in Schedules III through V without a prescription, as long as the drug is being delivered or administered directly to the patient for legitimate medical purposes.⁸⁴ In Massachusetts, the physician must be dispensing the medication for immediate treatment, which is defined as “that quantity of a controlled substance which is necessary for the proper treatment of the patient until it is possible for him to have a prescription filled by a pharmacy.”⁸⁵ This includes sample medications in Schedules II through V that have been supplied to the physician by pharmaceutical company representatives.

Massachusetts physicians are permitted to dispense up to a 30-day supply of Schedule VI sample medications.⁸⁶ Physicians may dispense larger supplies of sample medications, up to 90

⁸¹ The Federal and Massachusetts definitions of dispense are nearly identical. *See* 21 USC 802(10) and M.G.L. c. 94C, § 1.

⁸² 21 USC 822(e); 105 CMR 700.004(F). *See infra* Part I, Section 1, “Registration” for a detailed discussion of registration requirements.

⁸³ 21 USC 829(a).

⁸⁴ 21 USC 829; M.G.L. c. 94C, § 9(b) and 105 CMR 700.010(A)(2).

⁸⁵ M.G.L. c. 94C, § 9(b).

⁸⁶ 105 CMR 700.010(A)(1).

days, as part of a manufacturer's indigent drug program.⁸⁷ All sample medications dispensed to patients, including those provided as part of an indigent patient drug program, must be labeled.⁸⁸

Physicians may not issue prescriptions to obtain controlled substances for the purpose of dispensing or selling those drugs to patients.⁸⁹

Labeling

When a physician does dispense a controlled substance to a patient (and the substance is not administered by the physician or ingested in the physician's presence) the physician must package the controlled substance in a container and affix a label to the container that includes the following information:

- The physician's name and address;
- The date of dispensing;
- The name of the patient;
- The name, dosage and strength of the drug;
- Directions for use; and
- Any necessary cautionary statements.⁹⁰

Physicians who provide samples of Schedule VI drugs to their patients may keep a record of the drug dispensed in the patient's medical record, noting:

- The name, dosage and strength of the substance dispensed;
- The volume of units dispensed;
- The date of the dispensing; and
- The name and address of the person to whom the medication was dispensed.⁹¹

See also Appendix E, DPH Labeling Guidelines for Sample Prescription Drugs.

⁸⁷ M.G.L. c. 94C, § 9 and 105 CMR 700.010(A)(1).

⁸⁸ M.G.L. c. 94C §22 and 105 CMR 700.010

⁸⁹ M.G.L. c. 94C, §19(b).

⁹⁰ M.G.L. c. 94C, §22(b) and 105 CMR 700.010

⁹¹ 105 CMR 700.006(F)(5).

Recordkeeping Requirements

There are strict record-keeping requirements for physicians who stock controlled substances.⁹² Physicians who stock controlled substances in Schedules II and III must maintain records of:

- Their receipt and/or administration, including the names and quantities of the controlled substances,
- The name and address of the patient to whom it is administered or dispensed;
- The name, dosage and strength per dosage unit of each controlled substance; and
- The date of the administration or dispensing.⁹³

Inventories and records of Schedules II controlled substances that are dispensed to patients must be maintained in records separate from the inventories and records of other controlled substances dispensed.⁹⁴ Inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately, as well.⁹⁵ All drug records and inventories must be readily retrievable from the physician's ordinary business records.⁹⁶

Physicians must take a detailed, initial inventory of all controlled substances on hand for each location at which they dispense, with subsequent inventories done at least every two years.⁹⁷ All records related to controlled substances must be maintained at the registered location for at least two years and be available for inspection for a minimum of two years.⁹⁸

Physicians who provide samples of Schedule VI drugs to their patients must keep a record of the drug dispensed (the record may be kept in the patient's medical record), noting:

⁹² 21 USC 331(i), 333(b), and 353(c)-(d); 21 USC 824; 21 USC 827; 21 CFR 1304.21; M.G.L. c. 94C, § 9(d) and 105 CMR 700.006.

⁹³ 21 CFR 1304.03(b); 21 CFR 1304.22 and G.L. c. 94C, § 9(d).

⁹⁴ 21 USC 827(b) and 21 CFR 1304.04(g).

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ 21 CFR 1304.11(b); 21 CFR 1304.11(c) and 105 CMR 700.006.

⁹⁸ 21 USC 827(c); 21 USC 880; 21 CFR 1304.21 and 105 CMR 700.007.

- The name, dosage and strength of the substance dispensed;
- The volume of units dispensed;
- The date of the dispensing, and
- The name and address of the person to whom the medication was dispensed.⁹⁹

Security Requirements

All physicians who dispense controlled substances must have effective controls and procedures to guard against theft and diversion of controlled substances that they store.¹⁰⁰

Schedule II through V controlled substances must be in a securely locked, substantially constructed cabinet. Physicians are required to screen all employees or agents who will be work in or will be in areas where controlled substances are handled, and are prohibited from knowingly employing anyone who:

- Has been convicted of a felony offense related to controlled substances
- Has been denied a DEA registration
- Has had a DEA registration revoked; or
- Has surrendered a DEA registration for cause.¹⁰¹

Physicians should notify the DEA when they discovery any thefts or significant losses of controlled substances from stock and complete the necessary DEA forms to regarding the theft or loss.¹⁰² Physicians must also report drug theft, loss or any drug discrepancy to the Massachusetts

Drug Control Program (DCP) within 24 hours of discovery by:

- Telephoning DCP within 24 hours then mailing a Drug Incident Report (DIR) to the DCP within 7 days; or
- By visiting the DCP website, downloading a DIR form and faxing that form to DCP with 24 hours.¹⁰³

⁹⁹ 105 CMR 700.006(F)(5).

¹⁰⁰ 21 CFR Section 1301.71(a); 21 CFR 1301.75 and 105 CMR 700.005(A).

¹⁰¹ 21 CFR 1301.76(a) and 105 CMR 700.005(B).

¹⁰² 21 CFR 1301.76(b).

¹⁰³ 105 CMR 700.005(D).

The submission of the DIR form will satisfy DCP's requirements for both a telephonic and written report. Physicians should submit all subsequent relevant information they discover to the DCP.

Physicians may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III-V compounds may be transferred via invoice. In Massachusetts, the DCP is responsible for drug destruction. Physicians should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of two years.

5. SUPERVISION OF MID-LEVEL PRACTITIONERS AND OTHER HEALTH CARE PROFESSIONALS ENGAGED IN PRESCRIPTIVE PRACTICES

The term “mid-level practitioner” means an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he or she practices, to issue orders for a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, psychiatric nurse mental health clinical specialists, and physician assistants who are authorized to issue orders for controlled substances by the state in which they practice.¹⁰⁴ In Massachusetts, physicians are required to supervise the prescriptive practices of advance practice registered nurses and physician assistants.¹⁰⁵

Advance Practice Registered Nurses (Nurse Practitioners, Psychiatric Nurse Mental Health Clinical Specialists, and Nurse-Midwives)

Under the supervision of a licensed physician, nurse practitioners, psychiatric nurse mental health clinical specialists, and nurse-midwives are permitted to issue prescriptions pursuant to guidelines mutually developed and agreed upon by the advanced practice registered nurse and the supervising physician. The guidelines must be in accordance with the regulations of the Board of Registration in Medicine and the Board of Registration in Nursing.¹⁰⁶ The prescriptive practice of advanced practice registered nurses is defined and regulated by the Nursing Board.¹⁰⁷

¹⁰⁴ 21 CFR 1200.01(28).

¹⁰⁵ M.G.L. c. 112, §9E; M.G.L. c. 112, §80C and 80E.

¹⁰⁶ M.G.L. c. 112, §§ 80E and 80G; 244 CMR 4.00 *et. seq.*, and 243 CMR 2.10.

¹⁰⁷ 244 CMR 4.00 *et. seq.*

The supervising physician must have an unrestricted full license in the Commonwealth; have completed training in, be board-certified in or have hospital admitting privileges in a specialty area appropriately related to the advanced practice registered nurse's area of practice; and have a valid DEA certificate of registration and MCSR number.¹⁰⁸ In addition, if the physician is supervising a psychiatric nurse mental health clinical specialist, the physician must have completed training in psychiatry approved by the Accreditation Council for Graduate Medical Education (ACGME) or the Royal College of Physicians and Surgeons of Canada (RCPSC), or be Board-certified in psychiatry.¹⁰⁹

The supervising physician and advanced practice registered nurse must sign mutually developed and agreed-upon guidelines, the physician must review the advanced practice registered nurse's prescriptive practice at least every three months, and must provide ongoing direction to the nurse regarding the prescriptive practice.¹¹⁰

The Board's regulations set out the minimum requirements for the mutually agreed-upon written guidelines and remind physicians that the Board may request at any time an opportunity to review the guidelines.¹¹¹ The written guidelines must be very specific regarding the types of medications to be prescribed, any limitations on prescriptions, and when referral or physician consultation is required. In addition, there must be specific protocols for the initiation of intravenous therapies and Schedule II drugs.¹¹² While the regulations permit the physician and the advanced practice registered nurse to set the frequency of review of initial prescription of

¹⁰⁸ 243 CMR 2.10(2).

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ 243 CMR 2.10(4) and 2.10(5).

¹¹² 243 CMR 2.10(4)(8) and 244 CMR 4.22(3)(b) and 244 CMR 4.23(3)(b).

controlled substances, the physician must review the initial prescription of Schedule II drugs within 96 hours of the prescription.¹¹³

The Board urges physicians to remember that they are ultimately responsible for the prescriptive activities of the advanced practice registered nurses whom they supervise. The Board expects that physicians will only enter into supervision agreements with advanced practice registered nurses for whom they are able to provide supervision, practice review, and ongoing direction for the advanced practice registered nurse's prescriptive practice.

Physician Assistants

Physician assistants are permitted to engage in prescription practices under the supervision of a physician.¹¹⁴ The supervising physician must have an unrestricted full license in the Commonwealth; have completed training in, be board-certified in, or have hospital admitting privileges in a specialty area related to the physician assistant's area of practice; and have a valid DEA certificate of registration and MCSR number.¹¹⁵

The physician and physician assistant must sign mutually developed and agreed-upon guidelines; and the physician must review the physician assistant's prescriptive practice at least every three months and provide ongoing direction to the physician assistant.¹¹⁶

The Board's regulations set out the minimum requirements for the mutually agreed-upon written guidelines.¹¹⁷ The guidelines must include any limitations on medications to be prescribed, and describe the circumstances in which physician consultation and referral is required. The guidelines must include a mechanism to monitor the prescribing practices, and include protocols for the initiation of intravenous therapies and Schedule II drugs. In addition,

¹¹³ 243 CMR 2.10(4)9; 244 CMR 4.22(3)(c) and 244 CMR 4.23(3)(c).

¹¹⁴ M.G.L. c. 112, §9E.

¹¹⁵ 243 CMR 2.08(5)(a).

¹¹⁶ *Id.*

¹¹⁷ 243 CMR 2.08(5)(c).

the guidelines must specify the frequency of review, and in the case of prescriptions for Schedule II controlled substances, the physician must review the prescription within 96 hours after its issuance.¹¹⁸ The use of pre-signed prescription blanks or forms is prohibited.¹¹⁹

The Board urges physicians to remember that they are ultimately responsible for the prescriptive activities of the physician assistants whom they supervise. The Board expects that physicians will only enter into supervision agreements with physician assistants for whom they are able to provide supervision, practice review, and ongoing direction for the physician assistant's prescriptive practice.

Pharmacists

In January, 2009, the Commonwealth enacted the Collaborative Drug Therapy Management Act.¹²⁰ This law permits certain pharmacists and physicians to enter into a collaborative practice agreement, under which the pharmacist may then initiate, monitor, modify and discontinue a patient's drug therapy. The pharmacist must have advanced training and the scope of the collaborative practice must be within the scope of practice of the supervising physician.¹²¹ Collaborative practice agreements are allowed only in the following settings:

- Hospitals;
- Long Term Care facilities;
- Licensed inpatient or outpatient hospice settings;
- Ambulatory care clinics with onsite supervising by the attending physician and with a collaborating pharmacist who has no connection to any retail pharmacy; or
- Community retail drug businesses, with supervision by a physician according to the terms of the collaborative practice agreement and limited to the following: patients 18 years of age or older; an extension by 30 days of current drug therapy prescribed by the supervising physician; and administration of vaccines or the modification of dosages of medications prescribed by the supervising physician for asthma, chronic obstructive pulmonary disease, diabetes, hypertension, hyperlipidemia, congestive heart failure, HIV or AIDS and osteoporosis.

¹¹⁸ 243 CMR 2.08(5)(c)7.

¹¹⁹ 243 CMR 2.08(5)(d).

¹²⁰ Chapter 528 of the Acts of 2008.

¹²¹ M.G.L. c. 112, §24B 1/2.

The collaborative practice agreement must specifically name each disease being co-managed by the pharmacist and physician. In general, a patient must be referred by a supervising physician to that physician's collaborating pharmacist, must be given notice of the collaboration and must, as appropriate to the setting of the agreement, consent to the collaboration.

Any collaborative practice agreement in the retail drug business setting may only permit the prescription of Schedule VI controlled substances. Any collaborative practice agreement in such a setting, which allows the pharmacist to initiate prescriptions for referred patients of the supervising physician, must state that the pharmacist may only issue prescriptions for schedule VI controlled substances for a patient diagnosis specified in the supervising physician's individual referral of that patient. A copy of such a prescription shall be sent to the supervising physician within 24 hours.

A physician or physician group may hire pharmacists for the purpose of practicing collaborative drug therapy management under a collaborative practice agreement for the benefit of a patient of that physician or physician group. No retail pharmacy may employ a physician for the purpose of maintaining, establishing or entering into a collaborative practice agreement with a physician.¹²²

The Board of Registration in Medicine, the Board of Registration in Pharmacy, and the Drug Control Program are promulgating regulations to implement the provisions of the Collaborative Drug Therapy Management Act. A hearing on the proposed regulations was held on April 6, 2010.¹²³

¹²² M.G.L. c. 112, §24B 1/2.

¹²³ When promulgated, the proposed regulations will be found at 243 CMR 2.12 and 247 CMR 16.00.

6. GIFTS OR INDUCEMENTS FROM THE PHARMACEUTICAL INDUSTRY

The Commonwealth takes seriously the potential for impropriety or the appearance of impropriety which may occur when pharmaceutical companies or medical device manufacturers give gifts to physicians.

The AMA has issued an ethical opinion regarding gifts to physicians from representatives of the pharmaceutical and medical device manufacturing industry.¹²⁴ The entire opinion can be found online at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.shtml>. The AMA opinion recommends that physicians avoid accepting inappropriate gifts by focusing on whether the gifts primarily entail a benefit to patients, and ensuring that the gifts do not come with a *quid pro quo*, such as providing gifts in relation to the physician's prescribing practices.

In Massachusetts, there are specific prohibitions related to the giving of gifts to physicians by pharmaceutical and medical device manufacturing companies.¹²⁵ Of particular relevance to physicians are the standards regarding financial inducements to physicians by pharmaceutical or medical device manufacturing companies. Similar to the AMA opinion, these prohibitions are aimed at limiting the possibility of entangling the physician's practice of medicine with an expectation of *quid pro quo* from the pharmaceutical or medical device manufacturing company.

The rules prohibit or restrict many incentives previously provided by pharmaceutical or medical device manufacturing companies. Among the restrictions are the following:

- Pharmaceutical or medical device manufacturing companies may only provide or pay for meals for physicians that are modest and occasional in nature, and are directly related to an informational presentation;

¹²⁴ AMA Opinion 8.061 "Gifts to Physicians From Industry."

¹²⁵ M.G.L. c. 111N and 105 CMR 970.000 *et. seq.*

- No pharmaceutical or medical device manufacturing company may provide physicians with financial support related to the costs of attending CME events, conferences, or professional meetings;
- No pharmaceutical or medical device manufacturing companies may provide inducements or gifts to any physician who is not a salaried employee of the company.¹²⁶

As of July 1, 2010, and annually thereafter, every pharmaceutical or medical device manufacturing company must disclose to the Department of Public Health the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50, which the company provides, directly or through its agents, to any covered recipient, including physicians, in connection with the company's sales and marketing activities.¹²⁷ A person who knowingly and willfully violates these rules can be punished by a fine of up to \$5,000 for each violation.¹²⁸

¹²⁶ M.G.L. c. 111N and 105 CMR 970.000 *et. seq.*

¹²⁷ M.G.L. c. 111N.

¹²⁸ *Id.*

Part II - Boundaries of Acceptable Medical Practice

1. BASIC REQUIREMENTS OF ACCEPTABLE PRESCRIPTIVE PRACTICE

Valid Prescriptions

To be valid, a prescription must be issued for a legitimate medical purpose, by a practitioner in the usual course of his or her professional practice.¹²⁹

Legitimate Medical Purpose

The general standard for whether a prescription is issued for a legitimate medical purpose is often regarded as a question of whether the physician was acting in good faith in issuing the prescription.¹³⁰ There are several factors the Board looks at as indicia of the lack of good faith, including the following:

1. Failure to follow at least minimum professional procedure;
2. The physician permitting the patient to name the drug he desires;¹³¹
3. The physician expressing concern during a patient encounter as to how and where a prescription would be filled in a manner that does not indicate a good faith concern for his patient;
4. Repeated refills over relatively short periods;¹³²
5. General remarks of the physician indicating his or her experience with nontherapeutic uses of the drug and of drug enforcement actions and procedures;
6. Failure to schedule appropriate additional appointments for return visits and other factors indicating a lack of interest in follow-up care; and
7. Conversations and other circumstances that demonstrate that the physician knew that the drugs were not to be used for a therapeutic or medical purpose.¹³³

In the Usual Course of a Practitioner's Practice

To satisfy the requirement that a prescription be issued by a practitioner in the usual course of his professional practice, there must be a physician-patient relationship that is for the

¹²⁹ M.G.L. c. 94C, §19(a).

¹³⁰ *Commonwealth v. Noble*, 230 Mass. 83 (1918); *Commonwealth v. Miller*, 361 Mass. 644 (1972); and *Commonwealth v. Pike*, 430 Mass. 317 (1999).

¹³¹ The fact that a patient has named the drug he is eventually prescribed does not, by itself, necessarily make the prescription of that drug inappropriate.

¹³² The Board realizes that there are many situations where repeated refills over short periods are appropriate. Whether this indicates bad faith depends on the context in which the refills are given.

¹³³ See *In the Matter of Arthur E. Baer, M.D.*, Board of Registration in Medicine, Adjudicatory Case No. 205 (Final Decision and Order, July 14, 1978).

purpose of maintaining the patient's well being and the physician must conform to certain minimum norms and standards for the care of patients.¹³⁴ A minimum standard of proper medical practice requires that the physician establish a proper diagnosis and regimen of treatment. At a minimum, on first encounter with a patient, a physician must: 1) take and record an appropriate medical history; and 2) carry out an appropriate physical or mental status exam and record the results. The paramount importance of a complete medical history and a thorough and accurate physical examination is well established. The observance of these procedures as a function of the "usual course of professional practice" is of particular importance when controlled substances are to play a part in the course of treatment. It is the responsibility of the physician to prescribe drugs with proper regard for their action and potential dangers. Such procedures not only ensure that the patient obtains correct treatment but they may also prevent adverse reactions to drugs, which are a common cause of morbidity, and less commonly, mortality.

Failure to obtain an appropriate medical history and conduct an appropriate examination may not only have serious consequences for both the patient and the physician.¹³⁵ Careless diagnosis is as serious as careless treatment and frequently leads to allegations of misconduct. Physicians who have been disciplined by the Board for prescription practice violations have written prescriptions for potentially dangerous controlled substances without conducting any physical examinations or after conducting only cursory examinations.¹³⁶

¹³⁴ *In the Matter of Arthur E. Baer, M.D., supra.*

¹³⁵ The Board recognizes that covering and cross-covering for fellow physicians is part of the good practice of medicine and in such situations it may be perfectly appropriate to prescribe drugs to a patient whom the covering physician has never seen or examined. In these circumstances, the covering physician is relying on the treating physician's examination and diagnosis and this is permissible as long as the reliance is reasonable.

¹³⁶ Some specialists, such as psychiatrists in a private office setting, are permitted to prescribe drugs for mental ailments without conducting a physical examination where the general standards of good medical care indicate that a physical examination is not appropriate. Medical doctors, including psychiatrists, are permitted to treat illnesses outside their specialized area of practice where they have adequate training and the proper facilities to do so.

Beyond documenting appropriate medical histories and physical examinations, physicians must maintain medical records that are detailed enough in nature that the physician's clinical reasoning is discernable from his or her documentation. Treatment plans should be explicitly recorded. All patient visits and telephone calls relating to treatment should be documented. Prescriptions should be documented and changes in medications or dosage should be explained. These are just some of the rudiments of complete medical records.

Expedited Partner Therapy for the Treatment of Chlamydia

In order to combat the risk to the public health of untreated Chlamydia, the Legislature has passed a law permitting the prescribing and dispensing of prescription medication without a physical examination, in certain limited circumstances. Physicians, physician assistants, nurse practitioners, and certified nurse midwives who are authorized to prescribe and dispense prescription drugs, who diagnose infections due to *Chlamydia trachomatis* in individual patients, may prescribe and dispense prescription drugs to a patient's sexual partners for the presumptive treatment of Chlamydia infection without an examination of the patient's sexual partners.¹³⁷ Such prescribing practices are referred to as "Expedited Partner Therapy." In Massachusetts, Expedited Partner Therapy is permitted only for the treatment of Chlamydia.

This statute applies to physicians' own prescribing practices, and the prescribing practices of any mid-level practitioner whom a physician is supervising.

The statute requires DPH to consult with the Board in promulgating regulations authorizing Expedited Partner Therapy for the treatment of Chlamydia. The Board recognizes that the Legislature has authorized Expedited Partner Therapy in order to address a serious public health concern, but notes that it should not be interpreted as an abandonment of the Board's

However, a psychiatrist in a private office setting who does not have the facilities to conduct a proper physical examination should not be treating physical illnesses (such as back pain) where a physical examination is required.

¹³⁷ M.G.L. c. 111, §121B, inserted by the Acts of 2010, c. 131, §62, effective July 1, 2010.

long-held position that the act of prescribing medication must be performed only in the context of a bona fide provider-patient relationship, and after the physician has taken and recorded an appropriate medical history and an appropriate physical examination.

General Medical Standards and Preventing Medication Errors

As with every aspect of medical care, a physician's prescription practices should be guided by medical knowledge, best-practices, guidelines and consensus standards. Physicians should involve patients in decisions about treatment and adhere to requirements for informed consent. Physicians are expected to prescribe only within their scope of practice or expertise.

According to one estimate, in any given week four out of every five U.S. adults will use prescription medicines, over-the-counter (OTC) drugs, or dietary supplements, and nearly one-third of adults will take five or more different medications. Most of the time these medications are beneficial, or at least they cause no harm, but on occasion they do injure the person taking them.¹³⁸ Medication errors during hospitalization have been estimated to be 52 per 100 admissions, or 70 per 1,000 patient days.¹³⁹ One study of the ambulatory setting estimated the rate of adverse drug events to be 27 per 100 patients.¹⁴⁰

Establishing and maintaining a strong provider-patient partnership is essential to reducing medication errors. In addition, decreasing errors requires a comprehensive approach that includes participation by physicians, nurses, pharmacists, and others in the health care community.¹⁴¹ Inadequate communication between physicians and other health care providers about drug orders has been identified as one of the communication problems associated with

¹³⁸ *Preventing Medication Errors*, Philip Aspden, Julie A. Wolcott, J. Lyle Bootman, Linda R. Cronenwett, Editors, Institute of Medicine, 2006.

¹³⁹ Nebeker JR, et al. High rates of adverse drug events in a highly computerized hospital. *Arch Intern Med.* 2005; 165: 1111-1116.

¹⁴⁰ Gandhi TK, et al. Adverse drug events in ambulatory care. *N Engl J. Med.* 2003; 348 (16): 1556-1564.

¹⁴¹ *Preventing Medication Errors*, Philip Aspden, Julie A. Wolcott, J. Lyle Bootman, Linda R. Cronenwett, Editors, Institute of Medicine, 2006.

medication errors.¹⁴² The Board encourages physicians to understand their roles and responsibilities in preventing medication errors.

2. PRESCRIBING TO IMMEDIATE FAMILY MEMBERS

Board regulations prohibit physicians, “[e]xcept in an emergency, . . . from prescribing Schedule II controlled substances to a member of his immediate family, including a spouse (or equivalent), parent, child, sibling, parent-in-law, son/daughter-in-law, brother/sister-in-law, step-parent, step-child, step-sibling, or other relative permanently residing in the same residence as the licensee.”¹⁴³

The AMA has issued an Ethical Opinion on self-treatment and the treatment of families, and in that opinion state that physicians generally should not treat members of their immediate families.¹⁴⁴ The AMA notes that, among the risks that are raised when a physician establishes a physician-patient relationship with an immediate family member, are: professional objectivity may be compromised; the physician may fail to probe sensitive areas when taking the medical history or may fail to perform intimate parts of the physical examination; patients may feel uncomfortable disclosing sensitive information or undergoing an intimate examination when the physician is an immediate family member, and physicians may be tempted to treat problems that are beyond their expertise or training.

¹⁴² The Physician's Role in Medication Reconciliation; 2007 American Medical Association. Medication reconciliation is a method designed to improve communication. It provides a structured process for physicians and other health care providers to acquire and transfer accurate, detailed information about a patient's current prescribed medications, non-prescription and OTC drugs, or nutraceuticals. Careful medication reconciliation can reduce the rate of medication errors and adverse drug reactions.

¹⁴³ 243 CMR 2.07(19).

¹⁴⁴ *Code of Medical Ethics*, “Opinion 8.19 – Self-Treatment or Treatment of Immediate Family Members.” The AMA does recognize that “It would not always be inappropriate to undertake . . . treatment of immediate family members. In emergency settings or isolated settings where there is no other qualified physician available, physicians should not hesitate to treat . . . family members until another physician becomes available. In addition . . . there are situations in which routine care is acceptable for short-term, minor problems.”

Accordingly, the Board suggests that physicians consider refraining from prescribing all controlled substances for family members and significant others in non-emergency situations. Physicians who do choose to prescribe controlled substances for family members must take extra precautions to insure that this privilege is not abused. The same documentation and examination requirements applicable to patients who are not related to the physician apply when the physician is prescribing controlled substances to the physician's immediate family members. Physicians should document examination results, diagnosis and treatment plans carefully and accurately.

3. PRESCRIBING TO SELF

Physicians are prohibited from prescribing controlled substances in Schedules II through IV for their own use.¹⁴⁵

Physician self-prescribing presents even deeper concerns than prescribing to family members. The prescription of drugs to oneself creates an enormous potential for abuse. The Board has concluded that the potential for abuse of drugs in Schedules II through IV far outweighs the relatively minor inconvenience that is caused by requiring physicians to obtain prescriptions for their own use from other physicians.

4. INTERNET PRESCRIBING

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice.¹⁴⁶ This standard applies to any prescriptions issued or dispensed via the Internet. The Board has interpreted M.G.L. c. 94C, §19A in issuing Policy No. 03-06 – "Internet Prescribing."¹⁴⁷ The policy states that to be valid, a prescription must be issued in the usual course of the physician's professional practice, and within a physician-patient relationship that is for the purpose of

¹⁴⁵ 243 CMR 2.07(19).

¹⁴⁶ M.G.L. c. 94C, §19A.

¹⁴⁷ See Appendix B

maintaining the patient's well-being. In addition, the physician must conform to certain minimum norms and standards for the care of patients, such as taking an adequate medical history and conducting an appropriate physical and/or mental status examination and recording the results. "Issuance of a prescription, by any means, including the Internet or other electronic process, that does not meet these requirements is therefore unlawful."¹⁴⁸

The federal standards for distributing or dispensing controlled substances by means of the Internet are defined at 21 CFR 1300.04. While pharmacies are permitted to dispense controlled substances via orders made on the Internet, the original prescriptions must be issued for a legitimate medical purpose by a physician in the usual course of his or her professional practice.¹⁴⁹

In April 2002, the Federation of State Medical Boards (FSMB) issued "Model Guidelines for the Appropriate Use of the Internet in Medical Practice," which states, in part: "Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care." Two years prior to issuing this Model Guideline, in 2000, the FSMB established a National Clearinghouse on Internet Prescribing to collect and disseminate information on "rogue" Internet pharmacy websites, and to "assist regulatory authorities in their investigation of websites and associated physicians."¹⁵⁰ The FSMB defines "rogue" internet pharmacy websites, as "those that allow consumers to obtain prescription medications without an evaluation by a physician." The FSMB recognized this type of Internet prescribing "pose[s] an immediate threat to the public's health and safety," and noted that the health risks include:

¹⁴⁸ Policy No. 03-06 -- "Internet Prescribing."

¹⁴⁹ 21 CFR 1300.04(l)(1).

¹⁵⁰ *Rx Beat*, Spring 2005, Vol. 1 Issue 1. *Rx Beat* is the newsletter of the National Clearinghouse on Internet Prescribing and is available at www.fsmb.org.

- Adverse drug reactions and/or interactions;
- Misdiagnosis or delay in diagnosis;
- Failure to identify complicating conditions; and
- Misuse, abuse, and diversion of prescription medications, including controlled substances.

This type of “rogue” Internet prescribing should not be confused with “electronically transmitted prescriptions,” to local pharmacies or Internet pharmacies, which are discussed in Part I, Section 3 *infra*, “Prescriptions.”

In 2003, the AMA adopted a policy on Internet Prescribing.¹⁵¹ This policy calls for physicians who prescribe medications via the Internet to establish a valid patient-physician relationship. The AMA cautioned, “a physician prescribing medication across state lines must possess appropriate licensure in all jurisdictions where patients reside.”¹⁵² The AMA further stated, “Physicians who practice medicine via the Internet, including prescribing, should clearly disclose physician-identifying information on the web site, including (but not necessarily limited to) name, practice location (address and contact information), and all states in which licensure is held.”¹⁵³

5. PRESCRIBING FOR THE TREATMENT OF PAIN

The FSMB has issued a Model Policy for the Use of Controlled Substances for the Treatment of Pain (Model Policy), which the Board adopted in December, 2004. This “Guideline For the Use of Controlled Substances for the Treatment of Pain” is attached at Appendix D. In its Preamble, the policy states:

The Massachusetts Board of Registration in Medicine recognizes that principles of quality medical practice dictate that the people of the Commonwealth of Massachusetts have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with

¹⁵¹ AMA Policy H-120.949, Guidance for Physicians on Internet Prescribing.

¹⁵² *Id.*

¹⁵³ *Id.*

untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.¹⁵⁴

The Board encourages physicians to read and follow the policy, in treating patients' pain.

6. TREATING DRUG-DEPENDENT PERSONS

Treating patients for drug dependency usually requires specialized knowledge beyond the typical substance abuse training that is taught in medical school. Physicians should not undertake to treat patients for drug dependency or the psychological underpinnings of an addictive personality unless they have sufficient training to do so. Where the treating physician lacks specialized knowledge, patients should be referred to experts in drug dependency.

Physicians who use drugs to treat drug dependent persons for dependency are subject to special requirements under Massachusetts and federal laws.¹⁵⁵ Physicians interested in operating an opioid treatment program to provide Schedule II controlled substances for the treatment of opioid (narcotic) addiction should review Part I, Section 1, "Special Authorizations Required to Treat Addiction," and Part II, Section 7, "Office-Based Treatment of Opioid Addiction." To obtain the necessary applications for waivers and detailed information regarding opioid treatment program requirements, physicians should contact the DEA and the Massachusetts Drug Control Program. *See* Appendix A "Contact Information."

Physicians who are not specially registered with the DEA are permitted to administer narcotics to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment.¹⁵⁶ However, in such cases, not

¹⁵⁴ Guideline For the Use of Controlled Substances for the Treatment of Pain, adopted December, 2004.

¹⁵⁵ 21 CFR 1306.07(a); M.G.L. c. 111B, §§6, 6A, 6B; M.G.L. c. 111E § 7; and 105 CMR 164.000

¹⁵⁶ 21 C.F.R. c. 11, § 1306.07(b).

more than one day's medication may be administered at a time and such treatment may not continue for more than three days.¹⁵⁷

It should be emphasized that patients who legitimately take controlled substances for extreme pain can become tolerant to their medications. Such patients should not be considered "drug dependent." However, physicians should be aware of the following criteria for problematic opioid use:

- The patient displays an overwhelming focus on opiate issues during pain clinic visits that impede progress with other issues regarding the patient's pain. This behavior must persist beyond the third clinic treatment session.
- The patient has a pattern of early refills (three or more) or escalating drug use in the absence of an acute change in his or her medical condition.
- The patient generates multiple telephone calls or visits to the administrative office to request more opiates, requests early refills, or has problems associated with the opiate prescription. A patient may qualify with fewer visits if he or she creates a disturbance with the office staff.
- There is a pattern of prescription problems for a variety of reasons that may include lost medications, or stolen medications.
- The patient has supplemental sources of opiates obtained from multiple providers, emergency rooms, or illegal sources.¹⁵⁸

Physicians may be approached by patients for the specific purpose of securing drugs to support their dependency. Many physicians have been victimized by drug dependent persons when those tactics are employed skillfully. Drug dependent persons seeking controlled substances can be any age and often do not look "suspicious." Physicians should beware of transient patients, extremely persuasive patients, and patients who show little interest in the diagnosis and resist attempts to verify their medical history. These are common behaviors

¹⁵⁷ *Id.*

¹⁵⁸ These criteria are set out in the AMA Council on Science and Public Health Report 2 (1-08) "Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction."

among deceptive patients. Physicians who feel that they have been threatened into writing a prescription should immediately notify the police once the patient has left the office.

7. OFFICE-BASED TREATMENT OF OPIOID ADDICTION

The Board believes that the appropriate application of up-to-date knowledge and treatment modalities can successfully treat patients who suffer from opioid addiction and thereby reduce the morbidity, mortality and costs associated with opioid addiction, as well as public health problems such as infectious diseases. The Board encourages all physicians to assess their patients for a history of substance abuse and potential opioid addiction and to refer them to treatment as necessary.

Before any physician can treat opioid addicted patients in an office-based setting, the physician must apply for a waiver. *See infra* Part I, Section 1, "Special Authorizations Required to Treat Addiction." Once a physician has received that waiver, the Board expects that the physician will work within the boundaries of accepted professional practice for office-based treatment of opioid addiction. The Board encourages physicians who are engaged in office-based treatment of opioid addiction to review and follow the FSMB's Model Policy Guideline for Opioid Addiction Treatment in the Medical Office.¹⁵⁹

As articulated in the Preamble to the Model Policy Guideline:

The medical recognition and management of opioid addiction should be based upon current knowledge and research and includes the use of both pharmaceutical and non-pharmaceutical modalities. Prior to initiating treatment, physicians should be knowledgeable about addiction treatment and all available pharmacologic treatment agents as well as available ancillary services to support both the physician and patient. In order to undertake treatment of opioid addicted patients, in accordance with these guidelines, physicians must demonstrate a capacity to refer patients for appropriate counseling and other ancillary services.¹⁶⁰

¹⁵⁹ FSMB Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office, 2002. The Guidelines can be found online at: http://www.csam-asam.org/FSMB_vp.html.

¹⁶⁰ FSMB Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office, 2002

The Model Policy Guidelines set out the following standards and expectations regarding the treatment of an opioid addicted patient:

- Compliance with controlled substances laws and regulations;
- Evaluation of the patient;
 - A recent, complete and relevant medical history and physical examination must be documented in the medical record.
 - The record should document the suitability of the patient for office-based treatment.
- Treatment plan;
 - The written treatment plan should state objectives that will be used to determine treatment success.
- Informed consent and agreement for treatment;
- Periodic patient evaluation;
- Consultation;
 - The physician should refer the patient as necessary for additional evaluation and treatment.
 - The physician should pursue a team approach to the treatment.
- Accurate and complete medical records.

8. ENHANCING PATIENT COMPLIANCE

“Drugs don’t work in patients who don’t take them.”
- Former U.S. Surgeon General C. Everett Koop, M.D.

Surveys of patient compliance with prescription instructions are not encouraging. A survey done in 2006 revealed that nearly three out of every four Americans do not always take their prescription medications as directed.¹⁶¹ Of those surveyed:

- Over half said they had forgotten to take their medication;
- Nearly one-third had not filled a prescription they were given;
- Nearly one-third had stopped taking a medication before their supply ran out; and
- Almost one quarter had taken less than the recommended dosage.

Open avenues of communication between the physician and the patient can enhance patient compliance.¹⁶² Physicians should carefully describe to patients the purpose and use of

¹⁶¹ “Take as Directed: A Prescription Not Followed.” Research conducted by The Polling CompanyTM. National Community Pharmacists Association. December 15, 2006.

¹⁶² “An Rx For Better Outcomes, Lower Costs,” Rebecca J. Matchin, MD., American Medical News Opinion, December 7, 2009.

the drug, as well as any significant side effects that the patient may experience, and basic information on how to take the medication correctly. Physicians should encourage patients to ask questions, and should provide written information about medication.

Patient Medication Information sheets that describe individual prescription drugs in easy to understand terms are available for a nominal charge from the American Medical Association. The Board encourages physicians to provide this type of written information to patients to help patients become more informed participants in their own health care.

9. THE IMPORTANCE OF CONTINUING MEDICAL EDUCATION

Many physicians engage in improper and uninformed prescribing practices simply because they have not kept abreast of new developments in pharmacology and drug therapy. The Board urges all physicians to keep up-to-date on current information that affects the proper prescribing of controlled substances by taking Continuing Medical Education Courses.

**APPENDIX A –
CONTACT INFORMATION**

Massachusetts Controlled Substance Registration (MCSR)

Website: www.mass.gov/dph/dcp

Address: Drug Control Program
305 South Street, 2nd Floor
Jamaica Plain, MA 02130

Telephone: (617) 983-6700

Fax: (617) 524-8062

Email: dcp.dph@state.ma.us

DEA Registration

Website: www.DEAdiversion.usdoj.gov

Address: DEA Boston Field Office
JFK Federal Building
15 New Sudbury Street, Room E-400
Boston, MA 02203-0131

Telephone: (617) 557-2100

or

DEA Registration Section in Washington, D.C

Telephone: (800) 8982-9539

Substance Abuse Treatment Waivers:

Website: <http://buprenorphine.samhsa.gov/howto.html>

Address: Substance Abuse and Mental Health Services Administration
Division of Pharmacologic Therapies
Attention: Opioid Treatment Waiver Program
One Choke Cherry Road, Rm 2-1063
Rockville, MD 20857

Phone: 1-866-287-2728 (1-866-BUP-CSAT)

Federal Opioid Treatment Program (OTP)

Address: Division of Pharmacologic Therapies
Center for Substance Abuse Treatment
SAMHSA
1 Choke Cherry Rd.
Rockville, MD 20857

OTP Certification:

Website: <http://www.dpt.samhsa.gov/regulations/certification.aspx>

Contact: Sara Azimi-Bolourian, Public Health Advisor
Telephone: 240.276.2708
Fax: 240.276.2710

OTP Accreditation:

Website: <http://www.dpt.samhsa.gov/regulations/accreditation.aspx>

Contact: Alina Walizada, RPh, MS, Public Health Advisor
Telephone: 240 276-2755
Fax: 240 276-2710

Massachusetts Opioid Treatment Authority:

Website: <http://www.mass.gov/dph/bsas>

Address: Massachusetts Department of Public Health, Bureau of Substance
Abuse Services
250 Washington Street, Third Floor
Boston, MA 02108-4619
Telephone: (617) 624-5124
Fax: (617) 624-5395

**APPENDIX B –
POLICY 03-06 “INTERNET PRESCRIBING”**

(Adopted December 17, 2003)

INTERNET PRESCRIBING

A prescription for a controlled substance to be valid shall be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice....An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent [of this act].

M.G.L. c. 94C, Section 19(a)

This statutory language sets forth the minimum requirements that must be met in order for a prescription to be valid in the Commonwealth. To satisfy the requirement that a prescription be issued by a practitioner in the usual course of his professional practice, there must be a physician-patient relationship that is for the purpose of maintaining the patient's well-being and the physician must conform to certain minimum norms and standards for the care of patients, such as taking an adequate medical history and conducting an appropriate physical and/or mental status examination and recording the results. Issuance of a prescription, by any means, including the Internet or other electronic process, that does not meet these requirements is therefore unlawful.

**APPENDIX C –
2007-01 JOINT POLICY REGARDING ISSUANCE OF MULTIPLE PRESCRIPTIONS
FOR SCHEDULE II CONTROLLED SUBSTANCES; AND JOINT POLICY ON
PRESCRIBING AND DISPENSING OF DEXTRO- AND LEVO- AMPHETAMINES**

BOARD GUIDELINE

Guidelines on Certain Prescribing Practices

Adopted by the Board of Registration in Medicine on October 22, 2008

On December 19, 2007, the Drug Enforcement Agency issued a revised regulation, 21 C.F.R. §1306, allowing practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same Schedule II controlled substance. The Massachusetts Drug Control Program and the Board of Pharmacy have determined that issuing multiple Schedule II prescriptions, in accordance with the requirements of the amended federal regulation, is permissible under M.G.L. c. 94C.

The Board of Registration in Medicine concurs with the opinion expressed by the Massachusetts Drug Control Program and the Board of Registration in Pharmacy in their "Joint Policy regarding the Issuance of Multiple Prescriptions for Schedule II Controlled Substances."

The "Date of Issuance" referred to in G.L. c.94C, § 23 shall be the "Do Not Fill Before" date indicated by the prescriber. The "date written" under 94C, § 23 shall be the date the prescription was written and signed by the prescriber. Accordingly, each written prescription will become invalid thirty (30) days after its date of issuance, as is required by G.L. c. 94C, § 23 and the Board of Medicine's regulation at 243 C.M.R. 2.07(5).

The federal regulation states that "Where a prescription that has been prepared in accordance with Section 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the

prescription before that date." The DEA interprets this to mean that no verbal modifications can be made to the earliest date on which the Schedule II prescription may be filled.

243 CMR 2.07(5) states that "a licensee who violates M.G.L. c. 94C also violates 243 C.M.R. 2.00." A Massachusetts physician who prescribes in accordance with the Joint Policy regarding the Issuance of Multiple Prescriptions for Schedule II Controlled Substances" does not thereby violate any Board of Registration in Medicine law, regulation or policy on prescribing. Any conflict between the "Joint Policy regarding the Issuance of Multiple Prescriptions for Schedule II Controlled Substances" and any existing Board policy or regulation on prescribing shall be interpreted in favor of the "Joint Policy."

At the same time, the Board would like to clarify that a Massachusetts physician who prescribes in accordance with the "Joint Policy on Prescribing and Dispensing of Dextro-and Levo-Amphetamines," issued by the Drug Control Program and the Board of Registration in Pharmacy, does not thereby violate any Board law, policy or regulation on prescribing. The Drug Control Program and the Board of Registration in have determined that methylphenidate and single entity drug products containing the Dextro and/or Levo isomers of amphetamine may be dispensed in a sixty day supply when prescribed for inattention and impulsivity-hyperactivity disorder or narcolepsy. Any conflict between the "Joint Policy on Prescribing and Dispensing of Dextro- and Levo- Amphetamines" and any existing Board policy or regulation on prescribing shall be interpreted in favor of the "Joint Policy."

Joint Policy on Prescribing and Dispensing of Dextro- and Levo- Amphetamines

MDPH, Drug Control Program and Board of Registration in Pharmacy

Prescribers and pharmacists have asked whether Adderall®, a Schedule II amphetamine product, may be dispensed in a sixty day supply. Adderall® has federal Food and Drug Administration (FDA) indications for the treatment of Attention Deficit/Hyperactivity Disorder (ADHD) and narcolepsy. The Drug Control Program and the Board of Registration in Pharmacy have determined that methylphenidate and single entity drug products containing the dextro and/or levo isomers of amphetamine may be dispensed in a sixty day supply when prescribed for an inattention and impulsivity-hyperactivity disorder or narcolepsy. Quantity limits for controlled substances in Schedules II and III are set forth in M.G.L. 94C § 23(d) which reads, in part, as follows:

In regard to a controlled substance in Schedule II or III, no prescription shall be filled for more than a thirty-day supply of such substance upon any single filling; provided, however, that with regard to dextro amphetamine sulfate and methyl phenidate hydrochloride, a prescription may be filled for up to a sixty-day supply of such substance upon any single filling if said substance is being used for the treatment of minimal brain dysfunction or narcolepsy.

For the purposes of fulfilling the intent of the statute, the DCP and the Board find that:

1. the term "minimal brain dysfunction" means Attention Deficit/Hyperactivity Disorder (ADHD) or other accepted term for an inattention and impulsivity-hyperactivity disorder.
2. the term "dextro amphetamine sulfate" means a single entity drug product that contains the dextro and/or levo isomers of amphetamine and the salts thereof.

Therefore, a patient with narcolepsy, Attention Deficit/Hyperactivity Disorder (ADHD) or other inattention and impulsivity-hyperactivity disorder may now obtain a sixty day supply of Adderall® (there is no requirement that the diagnosis be written on the prescription).

This information is provided by the Drug Control Program within the Department of Public Health.

**APPENDIX D -
GUIDELINE FOR THE USE OF CONTROLLED SUBSTANCES FOR THE
TREATMENT OF PAIN**

**Model Policy for the Use of Controlled Substances for the Treatment of Pain
Federation of State Medical Boards of the United States, Inc.**

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., May 2004.

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions. Since adoption in April 1998, the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* have been widely distributed to state medical boards, medical professional organizations, other health care Regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The *Model Guidelines* have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the *Model Guidelines*.¹ Despite increasing concern in recent years regarding the abuse and Diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life.² The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies.³ Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of addiction and

dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

In April 2003, the Federation membership called for an update to its *Model Guidelines* to assure currency and adequate attention to the undertreatment of pain. The goal of the revised model policy is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from *Model Guidelines* to *Model Policy* to better reflect the practical use of the document.

The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. This policy is not meant to constrain or dictate medical decision-making. Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion. State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain as well as to update references and definitions of key terms used in pain management. The *Model Policy* is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

1. As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* and two (2) states have formally endorsed the *Model Guidelines*.
2. SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: *JAMA*, 274(20) (1995): p. 1591-1598.
3. A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, *J. of Law, Medicine, and Ethics*, 31 (2003): p. 128.

**Model Policy for the Use of Controlled Substances for the Treatment of Pain
Adopted by the Massachusetts Board of Registration in Medicine December 15, 2004**

Section I: Preamble

The Massachusetts Board of Registration in Medicine recognizes that principles of quality medical practice dictate that the people of the Commonwealth of Massachusetts have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with Pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Massachusetts Board of Registration in Medicine is obligated under the laws of the Commonwealth to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than

legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or

with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including o urine/serum medication levels screening when requested; o number and frequency of all prescription refills; and o reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction

**APPENDIX E –
DPH LABELING GUIDELINES FOR SAMPLE PRESCRIPTION DRUGS**

Regulations permit practitioners to dispense up to a 30 day supply of Schedule VI sample medications. Larger supplies of sample medications, up to 90 days, may be dispensed as part of a manufacturer's indigent drug program. Samples of Schedule II, III, IV or V medications are limited to a single dose or to a quantity needed for immediate treatment.

Labeling Requirements

Practitioners must label all sample medications dispensed to patients, including those provided as part of an indigent patient drug program (see M.G.L. c. 94C §22 and 105 CMR 700.010). Labels must contain the information described below; however, the method of labeling the medications may vary. For example, sample medications may be placed in a larger container such as an envelope with the required information written or typed on the front. Alternatively, the label may be a piece of paper affixed to the sample packaging or to a container holding the samples. The label may also be inserted inside a container holding the drug samples. This container may be a plastic or paper bag, an envelope or a box. However, the regulations specify that a container must hold only one type of drug sample. Thus, different drugs and their accompanying labels may not be mixed in a single container.

The following information must appear on the label provided to the patient:

- Practitioner's name and address
- Date of dispensing
- Name of the patient

In addition, the following information must be on the label if not included on the manufacturer's packaging of the sample medication. Physicians may use a combination of written information, labeling and counseling to provide this information.

- Name, Dosage form and strength of the sample medication
- Clear, simple and brief directions for use and any necessary cautionary statements
- Date on which medication will expire

Pharmaceutical companies may assist prescribers by providing pre-printed labels. Below are model labels prepared by the Department.

<p>Manufacturer's Logo (if desired) Practitioner's name/address Patient's Name Date Dispensed</p>

If not on the manufacturer's package, include:

<p>Drug Name Cautionary Statements Dosage Form and Strength Expiration Date Directions for Use</p>
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For further information, contact the Drug Control Program at (617) 983-6700.